

Effective Compliance Planning for Surgery Centers

Becker's ASC Conference



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To Be Discussed

1. OIG Core Compliance Program Components (“7 Core Elements”)
2. What’s in a Compliance Plan
3. Overview of Applicable Laws
4. Common Areas of Compliance Risk for ASCs
5. Best Practices; Operationalizing

OIG Core Compliance Program Components

OIG key recommendations for compliance programs (7 Core Elements):

1. Written **standards of conduct** and policies that promote compliance and address specific areas of potential fraud;
2. Designating a **chief compliance officer** and other bodies
3. Conducting *regular* and effective **training and education**;
4. Developing effective lines of **communication**;
5. Responding *appropriately* to detected offenses and developing **corrective action/disciplinary** action;
6. Conducting internal **monitoring** and auditing; and
7. **Enforcing** standards through well-publicized disciplinary guidelines.

What's in a Standard ASC Compliance Plan

1. Overview of applicable federal (and state) laws
2. Chief Compliance Officer duties and obligations
3. Acknowledgment Form
 - Signed by each owner and employee
 - Acknowledges he/she understands the Compliance Plan, has not been excluded from a federal health program, will be subject to discipline for violating Compliance Plan
4. Code of Conduct
 - Applicable to owners, Board members, and employees
5. Corporate Compliance Checklist
6. HIPAA Compliance Plan

Sample ASC Code of Conduct

1. Protect the confidential information of patients and families of patients.
2. Abide by all policies, as well as all state and federal laws and conditions of participation in health care reimbursement programs.
3. Will not encourage or participate, directly or indirectly, in activities such as theft, bribery, kickbacks, misappropriation, false statements, submission of false claims, discrimination, boycotts, price fixing, or violations of environmental or work place safety laws.
4. Will not make any payment, or offer to make any payment, whether in cash or in kind, to any physician, patient, hospital, facility, or other party in order to induce the referral of patients or other items or services to the Center.
5. Will not enter into relationships with any person or entity that may refer business to the Center unless such arrangements involve compensation for fair market value and the arrangements are fully compliant with all laws. No such arrangement shall take into account the volume or value of referrals by such person.
6. Will only bill for services in a manner that is legally appropriate. Owners and employees who are involved with billing functions will not submit any claims for amounts other than in accordance with the Center's policies.

Code of Conduct (continued)

7. Owners and employees who refer patients for services to the Center will only refer patients for services or procedures that are medically necessary or cosmetic in nature.
8. Treat all patients (including Medicare, Medicaid, and indigent patients) in a non-discriminatory manner.
9. ASC shall not offer shares or membership interests in exchange for referrals. Shares or membership interests in the Center may only be sold at fair market value.
10. Maintain compliance with the ambulatory surgery center Safe Harbor to AKS.
11. All distributions of Center earnings shall be based on the number of shares held by the owners and shall in no way be based on the volume or value of referrals.
12. Each owner shall notify patients of his or her financial interest in the Center if he or she refers such patients to the Center.
13. Each owner and employee shall treat all patients, Center personnel, and other members of the community with dignity, respect and compassion.
14. Maintain a safe working environment, will fulfill all duties in a safe manner, and will notify the proper Center personnel immediately of any hazard, injury, equipment problem, or other potential safety issue.
15. Any prohibited behavior will be reported to the appropriate Center personnel.

Overview of Applicable Laws

1. Anti-Kickback Statute, 42 U.S.C. § 1320a-7b
2. Physician Self-Referral Law (a/k/a the “Stark Law”), 42 U.S.C. § 1395nn
3. False Claims Act, 31 U.S.C. §§ 3729–3733
4. Health Insurance Portability and Accountability Act (“HIPAA”)
5. Non-Discrimination
6. Conditions for Coverage and Licensure

ASC Safe Harbor Enforcement

ASC Safe Harbors – Core Requirements

- Must not be related to volume or value of referrals
- No loans or loan guarantees by other investors allowed
- Distributions must be directly proportional to the amount of the capital investment of that investor
- All ancillary services must be directly and integrally related to primary procedures performed at the ASC and none may be separately billed to Medicare
- Must treat Medicare patients in a nondiscriminatory manner
- Patients must be fully informed of the physician's ownership
- For Single-Specialty ASCs: At least 1/3 of each physician investor's medical practice income from all sources for the previous fiscal year or previous 12 month period must be derived from the physician investor's performance of ASC eligible procedures (1/3 Income Test)
- For Multi-Specialty ASCs:
 - 1/3 Income Test, PLUS
 - At least 1/3 of the ASC procedures performed by each physician investor for the previous fiscal year or previous 12 month period must be performed at the ASC

Common Areas of Compliance Risk in ASCs

Selling Shares in an ASC

Tips to ensure an appropriate dialogue:

1. Do not offer less or more shares or a higher or lower price based on the number, volume or value of referrals a physician can generate.
2. Do not reallocate shares based on volume or value of referrals.
3. Do not focus on individual distributions being tied to the number of patient referrals. Never make any indications that could lead a potential investor to believe that referrals or performance will determine an individual's "piece of the pie." Focus on overall distributions and profits.
4. Physicians should not be allowed to invest based upon the fact that they can generate referrals for another physician who may use the center.
5. Avoid providing physicians with estimates as to the amount of revenue that will be generated from their referrals or from another physician's referrals.

Selling Shares in an ASC

Tips to ensure an appropriate dialogue:

6. When creating target lists, avoid focusing on the potential number of referrals, the physician's age, the growth potential of the physician's practice, etc.
7. Do not offer remuneration or special treatment under various disguises, such as directorship contracts or discounted lease arrangements, in order to induce investors.
8. Do not pressure physician investor to shift their current referral patterns.
9. Do not make any indications to investors that low-referring physicians will be pressured to withdraw.
10. Units should not be sold at a discount from their fair market value.
11. Investment by a group (practice or group of independent physicians) should be carefully vetted to ensure compliance

Physician Redemption Issues

Tips to ensure an appropriate dialogue:

1. Apply redemption rules consistently to all owners.
2. Do not redeem for “failing to bring enough cases” or “failing to bring profitable cases”.
3. Provide an owner notice of a redemption event and ample time and opportunity to cure (if applicable) any breach of the Operating Agreement.
4. Apply the safe harbor requirements consistently to all owners,
5. When redeeming, try to obtain a release from liability and indemnification from departing physician.

Medical Directorships/Leases & other Financial Arrangements with Referring Physicians

Tips to ensure an appropriate dialogue:

1. Ensure the relationship/arrangement is truly needed.
2. Do not consider the volume/value of referrals of a particular physician when entering into these arrangements.
3. Ensure any payment made thereunder is fair market value for the items/services being provided and support with third party valuation.
4. Require the medical director to record and report time spent performing the services for the ASC.
5. Ensure the equipment is required for services at the ASC and confirm that there are not other vendors providing better lease terms.
6. Ensure the space is necessary for the performance of the ASC.
7. Document the arrangement with a written agreement with a term of at least 1 year.
8. Attempt to comply with each element of an applicable safe harbor (Space Lease, Equipment Lease, Personal Services).
9. Ensure legal counsel has reviewed and approved the arrangement.

Third Party Arrangements

Also Consider These Types of Arrangements for Compliance

1. Anesthesia relationships and arrangements
2. Lab services arrangements
3. Local hospital services arrangements (e.g., lab, x-ray, emergency transfer)
4. Lease arrangements
5. Staffing arrangements
6. Back-office arrangements
7. Medical device/device manufacturer purchases
8. Physician-owned distributorships

Billing and Coding and Medical Necessity

1. OIG Billing and Coding Risk Areas

- A. Billing for items or services not rendered or not provided as claimed;
- B. Submitting claims for supplies and services that are not reasonable and necessary;
- C. Double billing that results in duplicate payment; and
- D. Billing for non-covered services as if covered.

2. Providers may only bill federally funded health care programs for “medically necessary” services and procedures that are properly ordered by a physician or other appropriately licensed person.

Employee Exclusions

- ASCs are responsible for ensuring that they do not employ or contract with excluded individuals or entities in any capacity or setting in which federal health care programs may reimburse for the ASC for those items or services furnished by those employees or contractors.
- Requirement to screen all current and prospective employees and contractors against OIG's List of Excluded Individuals and Entities.
- Some guidance suggests that screenings should be performed on a monthly basis

Best ASC Practices; Operationalizing

Practical Guidance for Health Care Governing Boards on Compliance Oversight

Guidance focuses on:

1. Roles of, and relationships between, the organization's audit, compliance, and legal departments;
2. Mechanisms and process for issue-reporting within an organization;
3. Approach to identifying regulatory risk; and
4. Methods of encouraging enterprise-wide accountability for achievement of compliance goals and objectives.

Emphasis placed on the Board having ultimate responsibility for organization, particularly compliance related issues.

Create a Culture of Compliance

1. Initial and ongoing education, distribution of compliance literature and periodic updates
2. All-hands' compliance meetings
3. Key leaders' attendance at compliance seminars
4. Board agenda includes compliance discussion
5. Routine monitoring and auditing, including billing and coding audits
6. Legal review of all contracts and other legally significant documents to ensure compliance regularly
7. Employee background checks and checks against the OIG exclusions list
8. Annual review of compliance plan
9. Communication of intent to investigate aggressively any suspected problems regarding compliance
10. Wall certificates and handouts to inform employees of who to contact for compliance issues
11. Keep a checklist of tasks to ensure performance of the above

Responding to Complaints

A complaint comes in or an employee or patient reports an issue

1. Always thank the employee or patient for the report
2. Always follow up on employee and patient reports (no matter what)
3. Utilize a tracking system to track all reports
4. Invite reporting of concerns
5. No retaliation; express that you will take seriously
6. No destroying documents (careful on “it’s the policy”); a hold notice
7. Get legal team together ASAP – 2 perspectives on the legal team. Former government perspectives and a trusted team (both internal and external)
8. Determine appropriate next steps

Responding to Investigations

An investigation commences through notice letter or the government appears at your door

1. Have a plan in place ahead of time
 - a) Will someone stay with investigators when they review documents?
 - b) Will you send staff home that day?
2. Do not hinder investigation
3. Communicate with legal as soon as possible – 2 perspectives on the legal team. Former government perspectives and a trusted team (both internal and external)
4. Advise employees of rights in talking to government (i.e., right to attorney, can have entity there too) – but do not obstruct
5. Establish early and ongoing communications with government
6. Always consider settlement
7. Budget and prepare for expenses

Compliance Concepts

1. If you can't write it, you cannot say it or do it.
2. If the real reason for something is illegal, no amount of dressing it up makes it legal.
3. If you cannot do it in the ASC, you can't do it outside of the ASC.
4. Cannot distribute shares or dollars based on referrals or cases – can't do it outside, i.e., in anesthesia company or relationship.
5. Can't swap streams of revenues, e.g., you get pathology if we get more ownership.
6. Must abide by operating agreement.
7. The 1% test.

Recap: The Three D's of Compliance

1. Deterrence: A well-trained workforce is less likely to engage in conduct which exposes your ASC to liability. This is true across the spectrum, including:
 - Enhancing adherence to billing and coding practices (minimizing underpayments, overpayments and fraud);
 - Avoiding violations of privacy policies and procedures; and
 - Avoiding violations of patient care policies and procedures.
2. Detection
 - Monitoring programs facilitate the early identification of problems.
 - Reduction in overpayment liability; placing the ASC in control.



3 D's cont'd.

3. Defense. If your ASC is investigated by the OIG or subject to allegations of fraud, the existence of an effective corporate compliance program may:



- reduce damage multipliers in False Claims Act cases
- reduce the duration of a Corporate Integrity Agreement (“CIA”)
- allow the company to enter into a less onerous monitoring agreement, i.e., a Certification of Compliance Agreement (“CCA”) instead of a CIA
 - shorter duration (3 years or less vs. 5 years)
 - no obligation to retain an independent review organization

Questions or Comments?

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